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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,323	07/09/2003	Laurence A. Cole	MBHB 03-411-A	1369

7590 03/16/2006

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EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,323	COLE, LAURENCE A.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-45* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a method of detecting the presence or absence of invasive trophoblast cells in a biological sample and diagnosing quiescent gestational trophoblastic disease in a biological sample by determining the percentage of hCG that is ITA, classified in class 435, subclass 4.

II. Claim 17, drawn to a method of detecting the presence or absence of invasive trophoblast cells in a biological sample by measuring the amount of ITA, classified in class 435, subclass 4.

III. Claims 18-22, drawn to a method of monitoring progression of quiescent gestational trophoblastic disease by determining the percentage of hCG that is ITA, classified in class 435, subclass 4.

IV. Claims 23-31, drawn to detecting the presence or absence of a germ cell tumor in a biological sample by determining the percentage of hCG that is ITA, classified in class 435, subclass 4.

V. Claims 32-36, drawn to a method of detecting the presence or absence of a germ cell tumor in a biological sample by measuring the amount of ITA, classified in class 435, subclass 4.

VI. Claims 37-45, drawn to monitoring the progression of a germ cell tumor in a biological sample by determining the percentage of hCG that is ITA, class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I, II, III, IV, V, and VI are materially distinct methods, which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. In the instant case, Groups I-VI involve different steps and different objectives. For example, Group I involves the steps of determining the presence or absence of invasive trophoblastic cells and diagnosing quiescent gestational trophoblastic disease by measuring the levels of hCG and ITA and determining the percentage of hCG that is ITA. However, Group II is distinct in that it employs a different method that only entails the measurement of ITA in a biological sample. Additionally, the simple determination of the presence or absence of cells in a sample is substantially different from diagnosing a disease state. Diagnosis implies the involvement of a skilled practitioner such as a physician where detection need only involve technical staff. The method of Group III is distinct in that it is directed to a method of monitoring the progression of quiescent gestational trophoblastic disease, which involves the steps of monitoring the percentage of hCG that is ITA in biological samples at different time points.

The inventions of Groups I, II, and III are distinct from the inventions of Groups IV, V, and VI in that Groups I-III are directed to gestational trophoblastic disease while Groups IV-VI are directed to germ cell tumors. Gestational trophoblastic disease and germ cell tumors are distinct diseases and are likely to have distinct etiologies and pathologies.

The method of Group IV involves the steps of determining the presence or absence of a germ cell tumor in a biological sample by measuring the levels of hCG and ITA and determining the percentage of hCG that is ITA. However, Group V is distinct in that it employs a different method to determine the presence of a germ cell tumor that only entails the measurement of ITA in a biological sample. The method of Group VI is distinct in that it is directed to a method of monitoring the progression of a germ cell tumor, which involves monitoring the percentage of hCG that is ITA in biological samples at different time points.

Furthermore, searching all of the inventions of Groups I-VI would invoke a burdensome search. Although the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig Ph.D.
Examiner
Art Unit 1642

PJR

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER